Before the Federal Communications Commission Washington, D.C. 20554

In the Matters of)
Review of the Commission's Part 95 Personal Radio Services Rules) WT Docket No. 10-119
Petition for Rulemaking of Garmin International, Inc.) RM-10762)
Petition for Rulemaking of Omnitronics,) RM-10844

PETITION FOR RECONSIDERATION OF MEDTRONIC, INC.

Medtronic, Inc. ("Medtronic"), pursuant to Section 1.429 of the Commission's rules, ¹ hereby submits this Petition for Reconsideration of the Report and Order issued in the above-captioned proceeding to update and reorganize the rules governing the Personal Radio Services. ² Though the *PRS Order* intended to "make no substantive changes" to the Medical Device Radiocommunications ("MedRadio") Service, ³ several rule revisions meant as ministerial stray from this objective and may be susceptible to interpretations that could contradict or modify significantly the current MedRadio rules. Consistent with the stated intent of this proceeding, Medtronic requests that the Commission revise the new rules as set forth in Attachment A to avoid unintended consequences for the MedRadio Service. ⁴

¹ 47 C.F.R. § 1.429.

² Review of the Commission's Part 95 Personal Radio Services Rules, Report and Order, 32 FCC Rcd 4292 (2017) ("PRS Order").

 $^{^3}$ Id., ¶ 81. Please note that this Petition for Reconsideration is limited to discussion of MedRadio Service devices and rules for the 401-406 MHz band.

See Attachment A. In this Petition, "new" rules reference the rules adopted in the *PRS Order*. "Current" rules reference the rules in effect prior to September 28, 2017, the effective date of the rules adopted in the *PRS Order*.

I. BACKGROUND.

Medtronic is an internationally recognized pioneer and leader in the development of numerous medical devices such as cardiac pacemakers, defibrillators, infusion pumps, and neural stimulators, some of which are MedRadio Service devices. Medtronic's mission involves identifying new ways to enhance global healthcare, primarily by improving lives through its medical technologies and solutions. As part of this mission, Medtronic creates a variety of sophisticated medical devices and services that incorporate communications capabilities. Many of these devices, for example, allow physicians to download data seamlessly from implanted devices to serve better the healthcare needs of patients. The Commission has recognized that these devices play a transformative role in medicine, providing "benefits to patients in terms of mobility and comfort" while also significantly "reducing healthcare costs."

II. THE COMMISSION DID NOT INTEND TO MAKE SUBSTANTIVE CHANGES TO THE MEDRADIO RULES FOR THE 401 – 406 MHZ BAND AND SHOULD REVISE ITS RULES APPOPRIATELY.

The *PRS Report and Order* made clear the Commission's intent with regard to current MedRadio service rules: "Other than the reorganization of the rules to fit the new [subpart] template, we make no substantive changes to the MedRadio Service." Such intention flows directly from established FCC policy, meant to "recognize and facilitate the significant advances in wireless medical technologies that are revolutionizing treatment for a wide variety of medical

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Medtronic, Inc., based in Minneapolis, Minnesota, is a subsidiary of Medtronic plc. For more information please visit the link: www.medtronic.com

Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, 16 FCC Rcd 4543, ¶ 2 (2001).

⁷ *PRS Order*, \P 81.

conditions and creating new health care models to benefit all Americans." MedRadio device innovation can "significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions," "hold[s] the promise of safer, less invasive, and more effective treatment options," and "could result in lower medical costs and extend the time between hospital visits and surgical procedures."

Nevertheless, several new regulations adopted in the *PRS Order* can be interpreted to run counter to the Commission's stated objective for MedRadio in this proceeding and the agency's broader policy goals for innovative medical device technology. Given that the FCC did not contemplate substantive changes for MedRadio in the notice of proposed rulemaking in this proceeding or the *PRS Order*, ¹⁰ Medtronic requests appropriate revisions as set forth in Attachment A. ¹¹ In addition, Attachment A proposes changes to sections that contain typographical errors.

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⁸ *Medical Device Radiocommunication Service in the 413-457 MHz Band*, 26 FCC Rcd 16605, ¶ 2 (2011).

⁹ *Id.*, ¶ 3.

See generally Review of the Commission's Part 95 Personal Radio Services Rules, Notice of Proposed Rulemaking and Memorandum Opinion and Order on Reconsideration, 25 FCC Rcd 7651 (2010); PRS Order, ¶ 81.

See Attachment A. Note that Medtronic's proposed rule changes appear as track changes.

III. CONCLUSION.

The *PRS Order* did not intend to make substantive changes to the MedRadio rules. By this petition for reconsideration, Medtronic requests that the Commission make certain rule revisions to remain consistent with this intent.

Respectfully submitted,

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ATTACHMENT A

§ 95.303 Definitions.

Authorized bandwidth. For other than the 401-406 MHz MedRadio frequency band, the maximum permissible occupied bandwidth of an emission. For the 401-406 MHz MedRadio frequency band, the maximum permissible bandwidth of an emission.

Analysis: Though the new rules define "occupied bandwidth," its measurement is not required in the current MedRadio rules. As a result, requiring measurement of "occupied bandwidth" for MedRadio devices would constitute a substantive change. Note that except for using the term "emission," as the new rule does, rather than "transmission," the second sentence of this definition mirrors language currently included in Appendix 1 to Subpart E of Part 95.¹

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See Appendix 1 to Subpart E of Part 95—Glossary of Terms.

§ 95.2503 Definitions, MedRadio.

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

Analysis: The use of "if" rather than "of" appears to be a typographical error.

§ 95.2533 Prohibited MedRadio uses.

(e) Except as provided in § 95.2559(b), no MedRadio implant or body-worn transmitter shall transmit except in response to (i) a transmission from a MedRadio programmer/control transmitter or (ii) a non-radio frequency actuation signal generated by a device external to the body with respect to which device the MedRadio implant or body-worn transmitter is used.

Analysis: The second use of the word "device" may produce confusion. Its deletion returns this new rule to language included in § 95.1209(b) of the current rules.

§ 95.2557 MedRadio duration of transmissions.

- (b) MedRadio transmitters may transmit in the 401–406 MHz band in accordance with the provisions of § 95.2559(b)(2) and § 95.2559(b)(3) for no more than 3.6 seconds in total within a one hour time period without the communications of data.
- (c) MedRadio transmitters may transmit in the 401–406 MHz band in accordance with the provisions of § 95.2559(b)(4) for no more than 360 milliseconds in total within a one hour time period without the communications of data.

Analysis: The Commission appears to have added the phrase "without the communications of data" to §§ 95.2557(b) and (c) to be stylistically congruent with new § 95.2557(a). While a provision limiting transmissions without data is appropriate for § 95.2557(a) because it relies on a Listen Before Talk ("LBT") spectrum access protocol, for (b) and (c), the text might be construed erroneously as implying no time limit on transmissions with data for devices that do not employ an LBT protocol. As the current rule limit of 3.6 seconds applies to any type of transmission (with or without data), deleting "without the communications of data" avoids confusion and superfluous text. By extension, deletion of the text returns this section to language included in current § 95.1209(d).

§ 95.2559 MedRadio channel access requirements.

(a) Frequency monitoring in the 401–406 MHz band.

[...]

- (6) When a channel is selected prior to a MedRadio communications session, it is permissible to select an alternate authorized channel for use if communications are interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:
- (i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.
- (ii) The detected power level during this 10 millisecond or greater monitoring period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.
- (iii) In the event that this alternate channel provision is not used by the MedRadio system, or if the criteria in sub-paragraphs (i) and (ii) above are not met, any alternate authorized a channel must be selected using the access criteria specified in paragraphs (a)(1) through (a)(5) of this section.

Analysis: The use of the word "authorized" in § 95.2559(a)(6) implies fixed channelization in the MedRadio frequency allocation, for which the 401-406 MHz MedRadio rules do not provide. The deletion of "authorized" removes this inference and returns to language included in current § 95.627(a)(5). Likewise, the use of "any alternate authorized" in § 95.2559(a)(6)(iii) implies fixed channelization and multiple alternate channels. Per new Rule 95.2559(a)(6), only one alternate channel is permitted. The deletion of "any alternate authorized" returns to language included in current § 95.627(a)(5)(iii) and allows the rule to fulfill its original intent whereby new § 95.2559(a)(6)(iii) serves as an exception clause to address the case where the criteria in sub-paragraphs (i) and (ii) are not met or the alternate channel provision is not used. The prosed language, however, is not intended to be a recommendation that a single alternate channel be selected under new § 95.2559(a)(6)(iii).

§ 95.2579 MedRadio unwanted emissions limits.

- (c) Attenuation requirements, 402–405 MHz. For MedRadio transmitter types designed to operate in the 402-405 MHz band, unwanted emissions must be attenuated below the maximum permitted transmitter output power by at least:
- (1) 20 dB, on any frequency within the 402–405 MHz band that is more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy occupied bandwidth;
- (2) 20 dB, on any frequency between 401.750 MHz and 402.000 MHz, and on any frequency between 405 MHz and 405.250 MHz.
- (d) Attenuation requirements, 401–402 MHz, 405–406 MHz. For MedRadio transmitter types designed to operate in the 401–402 MHz band or 405–406 MHz band, the power of unwanted emissions must be attenuated below the <u>maximum permitted</u> transmitter output power by at least:
 - (1) 20 dB, on any frequency within the 401–401.85 MHz or 405–406 MHz bands that is:
- (i) More than 75 kHz away from the center frequency of the <u>spectrum the transmission is</u> <u>intended to occupy occupied bandwidth</u> if the MedRadio transmitter type is operating on a frequency between 401.85 and 402 MHz; or,
- (ii) More than 50 kHz away from the center frequency of the <u>spectrum the transmission</u> <u>is intended to occupy-occupied bandwidth</u> and 100 kHz or less below 401 MHz or above 406 MHz.

 $[\ldots]$

(g) *Measurements*. Compliance with the limits in paragraphs (c), (d) and (e) of this section is based on the use of measurement instrumentation using a peak detector function with an instrument <u>resolution reference</u> bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

Analysis: As explained above, requiring measurement of "occupied bandwidth" for MedRadio devices would constitute a substantive change. The three revisions in this section replace "occupied bandwidth" with the phrase "spectrum the transmission is intended to occupy" consistent with language in current § 95.635(d)(4) and § 95.635(d)(5). Likewise, for § 95.2579(d), inserting the phrase "maximum permitted" returns this section to language consistent with current §§ 95.635(d)(4) and (5). This insertion is required to accommodate low-power transmitter architectures.

For § 95.2579(g), replacing the word "reference" with "resolution" returns this section to language in current § 95.635(d)(8). This change avoids technical inaccuracies that would result from the current wording.